K130088
Page 1 of 4

Exhibit 5 510(k) Summary

Date of Summary Preparation: Dec 21, 2012

JUL 18 2013

1. Submitter and US Official Correspondent

Submitter:	GENORAY Co., Ltd.
Address:	#512, Byucksan Technopia 434-6, Sangdaewon 1-dong, Jungwon-gu, Seongnam-city Gyeonggi-do, 462-716, Korea
Telephone No.:	+82-31-740-4100
Fax:	+82-31-737-8018

Official Correspondent (U.S): Jae Kim - Business Manager

Correspondent :	GENORAY America Inc.
Address:	1073 N. Batavia St. Orange, CA 92867, USA
Telephone No.:	855-436-6729
Fax:	714-786-8919
Email:	jac@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name: Digital x-ray sensor system / PortView
Common/Usual Name: Digital x-ray sensor system / Intraoral X-ray sensor system
Classification Name: Digital x-ray sensor(Intraoral sensor) system to capture Extraoral X-ray source
Product Code: MUH
Device Class: Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

Company	Device Name	K-Number
Schick Technologies, Inc.	Schick Computed Oral Radiology System, CDR	K072134
Edlen Imaging LLC	Gemini DUSB	K103290

5. Description of the Device

The digital x-ray sensor system, PortView produces instant, digital, intra-oral x-ray images of a patient's mouth for diagnosis of diseases of the teeth and oral structures. It consists of digital intraoral sensors and image processing software as followings.

Digital Intraoral sensor: is an indirect light converting digital X-ray detector. Incident X-rays are converted to visible light by a scintillating device. (material) such as CsI(Cesium Iodide), the light is coupled optically to a light detection imager which is based on CMOS technology.
The sensor supports USB 2.0 Direct connectivity to personal computers and or laptops.

Image processing software: provides various functions such as Image acquisition, Image search, Image Processing including Enhancement, 2D analysis (Zoom, Rotate, and Measurement) and Image Printing & Saving and DICOM 3.0 application.
It can operate on any hardware platform which meets the minimum requirements that Intel Pentium Dual-Core 2.5GHz with Windows XP operating system.

Items \ Product		PortView
Manufacturer		GENORAY Co., Ltd.
Product Name		PortView
510(k) No.		-
Implementation		Software and Sensor
Indications for use		PortView is indicated for use in acquiring images of patient teethes. It is intended for intra oral x-ray examinations and produces instant, digital, intra-oral x-ray images of a patient's mouth for diagnosis of diseases of the teeth and oral structures.
Intra oral sensor	Size (mm)	Size1: 36.73 X 24.35 Size2: 42.8 X 30.49
	Active Area (mm^2)	Size1: 600 Size2: 900
	Technology	CMOS
	Interface to PC	USB 2.0
	Dynamic Range	4096:1
	Cable length(m)	3
Software	Specification	1. Software name : PortView 2. Software version : 1.0 3. File size : 100MB 4. Language : C++ 5. DICOM 3.0 Support
	CPU	Intel Pentium Dual-Core 2.5GHz(E5200) or higher
	Memory	1GB or higher
	HDD	10GB or higher (Client) 100GB or higher
	VGA	Onboard chipset or higher
	OS	Windows XP or higher
	DICOM Compliance	DICOM 3.0
	IMAGE ARCHIVE	DCM, BMP, JPG, PNG
	WINDOWING	Adjust the Window width and level for contrast windowing parameters.
	USB Port	USB 2.0

6. Indications for use/ Rationale for Substantial Equivalence

The PortView is to be used as a digital intra oral sensor system of X-rays in Dental radiography.

The PortView shares the same indication for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed above No.4.

There are many independent manufacturers of intraoral x-ray dental radiography systems in the United States today. One is Schick Computed Oral Radiology System, CDR by Schick Technologies, Inc. (K0752134). The other currently marketed device is the Gemini DUSB by Edlen Imaging LLC. (K103290)

A comparison table for the different systems is available in the section on Substantial Equivalence and No.7 below.

The device has been tested by a third party and found to meet the international safety standards established by the IEC 60601-1, further details available in the section on Test report.

7. Substantial equivalence chart (Technological Characteristics)

Manufacturer	GENORAY Co., Ltd.	Schick Technologies, Inc.	Edlen Imaging LLC
Product Name	PortView	Schick Computed Oral Radiology System. CDR	Gemini DUSB
Implementation	Software and Sensor	Software and Sensor	Sensor Only
Sensor size (mm)	Size1: 36.73 X 24.35 Size2: 42.8 X 30.49	Size 1: 31 X 22 Size 2: 37 X 24 Size 2: 43 X 30	Size1: 36.73 X 24.35 Size2: 42.8 X 30.49
Sensor Active Area (mm^2)	Size1: 600 Size2: 900	Size1: 432 Size2: 600 Size3: 921	Size1: 600 Size2: 900
Technology	CMOS	CMOS	CMOS
Interface to PC	USB 2.0	USB 2.0	USB 2.0
Dynamic Range	4096:1	4096:1	4096:1
Cable length(m)	3	2	3
CPU	Intel Pentium Dual-Core 2.5GHz(E5200) or higher	Intel Pentium IV or AMD 3GHz or higher	2.0 GHz Pentium 4
Memory	1GB or higher	1 GB	1GB
HDD	10GB or higher (Client) 100GB or higher	80 GB HD	80GB
OS	Windows XP service pack 2 or higher	Windows XP Professional or Windows Vista Home Premium	Windows XP Pro / 7
DICOM Compliance	DICOM 3.0	DICOM 4.5	DICOM 3.0
Monitor Settings(Min.)	1024 X 768	1024 X 768	1024 X 768

8. Safety, EMC and Performance data

The basic safety and essential performance testing according to standard IEC 60601-1 were performed. EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory.

And the result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Conclusion

The PortView is determined to be substantially equivalent to other legally marketed devices in the United States. They are the Schick Computed Oral Radiology System, CDR by Schick Technologies, Inc. and the Gemini DUSB by Edlen Imaging LLC.

We believe that the PortView is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

GENORAY Co., Ltd.
% Mr. Jae Kim
Business Development Manager
GENORAY America, Inc.
1073 N. Batavia Street
ORANGE CA 92867

Re: K130088
Trade/Device Name: PortView, digital x-ray sensor system
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: April 23, 2013
Received: April 26, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

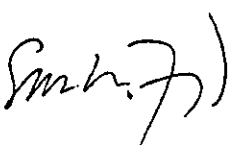
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130088

Device Name: Digital x-ray sensor system, PortView

Indications for Use:

PortView is indicated for use in acquiring images of patient teeth. It is intended for intra oral x-ray examinations and produces instant, digital, intra-oral x-ray images of a patient's teeth for diagnosis of diseases of the teeth and oral structures.

The digital x-ray sensor system, PortView consists of Image acquisition part as an Intraoral Sensor and Image processing Software which provides functions such as Image acquisition, store, and search and connects to Network. And the software can also display images from intra oral video cameras.

Prescription Use ___V___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130088